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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/602,212	06/23/2000	Ursula Buchholz	15280-398100US	9937

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12/07/2001

Jeffrey J King
Townsend and Townsend and Crew LLP
Two Embarcadero Center
8th Floor
San Francisco, CA 94111-3834

EXAMINER

BROWN, STACY D

ART UNIT

PAPER NUMBER

1648

12

DATE MAILED: 12/07/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/602,212

Applicant(s)

BUCHHOLZ ET AL

Examiner

Stacy S Brown

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-101 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-101 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

1. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to **Group Art Unit 1648**.

2. Claims 1-101 are pending.

Election/Restrictions

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-29, 46-47, 57-82, 85-87, 90-92, 95 and 98-101, drawn to a chimeric human-bovine RSV, classified in class 424, subclass 199.1.
- II. Claims 30-34, 83 and 93, drawn to a chimeric human-bovine RSV with additional attenuating mutations, classified in class 424, subclass 205.1.
- III. Claims 35-42, 84 and 96-97, drawn to a chimeric human-bovine RSV with additional phenotypic changes, classified in class 424, subclass 205.1.
- IV. Claims 43-45 and 94, drawn to a chimeric human-bovine RSV/PIV, classified in class 424, subclass 211.1.
- V. Claims 48-56, drawn to a method of stimulating the immune system, classified in class 435, subclass 69.3.
- VI. Claims 88-89, drawn to a method for producing RSV, classified in class 435, subclass 69.1.

If Applicant elects Group I, further restriction is required in claims 98-99. This is not a species election. Applicant must elect one of the following viruses from claim 98 and the corresponding proteins in claim 99:

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- A. Measles virus, HA and F proteins
- B. Subgroup A and B RSV, F, G, SH and M2 proteins
- C. Mumps virus, HN and F proteins
- D. Human Papilloma viruses, L1 protein
- E. HIV 1 and 2, gp160 protein
- F. Herpes Simplex viruses, gB, gC, gD, gG, gH, gI, gJ, gK, gL and gM proteins
- G. Cytomegalovirus, gB, gC, gD, gG, gH, gI, gJ, gK, gL and gM proteins
- H. Rabies virus, G protein
- I. Epstein Barr virus, gp350 protein
- J. Filoviruses, G protein
- K. Bunyaviruses, G protein
- L. Flaviviruses, E and NS1 proteins
- M. Alphaviruses, E protein
- N. Influenza viruses

The inventions are distinct, each from the other because of the following reasons:

a) Inventions I-IV are all are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to different products having different structures, functions and modes of operation. Inventions I-IV are drawn to chimeric RSVs having various mutations for attenuations and additional phenotypic changes. Additionally, invention IV is drawn to a chimeric RSV/PIV, which differs from invention I-III because of the presence of PIV. Similarly,

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inventions A-N are drawn to different combinations of chimeric viruses involving more than RSV from humans and bovines. These chimeric viruses of PIV and viruses A-N constitute different products having different structures, functions and effects. They are not disclosed as capable of use together.

b) Inventions (I-IV) and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as in an assay to detect the presence of RSV antibodies.

c) Inventions (I-IV) and VI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different process, such as ligation of the heterologous proteins.

d) Inventions V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to a methods of using RSV and producing RSV. These methods have different method steps, modes of operation, function and effect. The methods are not disclosed as capable of use together.

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Because these inventions are distinct for the reasons given above and the literature and sequence search required for one group is neither required nor co-extensive for any other group and therefore burdensome, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Papers relating to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 located in Crystal Mall 1. The Fax number for Art Unit 1648 is (703) 308-4426. All Group 1600 Fax machines will be available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Stacy S. Brown, whose telephone number is (703) 308-2361. The Examiner can normally be reached on Monday through Friday and alternate Wednesdays from 6:30 AM-4:00 PM, (EST). If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, James C. Housel, can be reached at (703) 308-4027. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Stacy S. Brown
December 6, 2001



HANKYEL T. PARK, PH.D
PRIMARY EXAMINER